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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,270	05/23/2005	Hidenori Nakajima	260617US0PCT	5020

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
HAMIDINIA, SHAWN A	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/511,270	NAKAJIMA ET AL.	
	Examiner	Art Unit	
	Shawn Hamidinia	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-2, 4-5, 7,18 drawn to polynucleotide sequences, a vector, and a transformant.

Group II, claims 3, 13 drawn to polypeptides encoded by the polynucleotide sequences and a medicament which comprises the peptide.

Group III, claim 6 drawn to a process of producing the polypeptide.

Group IV, claim 8 drawn to an antibody to the peptide.

Group V, claim 9 drawn to an immunological detection method of a peptide.

Group VI, claim 10 drawn to a method for screening a sugar production-regulating substance.

Group VII, claim 11 drawn to a different method for screening a sugar production-regulating substance.

Group VIII, claims 12 drawn to a medicament that contains the compound obtained from the screening method.

Claim 15 links Groups II and VIII. The restriction requirement between the linked groups is subject to the nonallowance of the linking claim(s), claim 15. Upon the allowance of the linking claim(s), the restriction requirement as to the linked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA) 1971). See also MPEP § 804.01.

Group IX, claim 14 drawn to a medicament that contains an anti-sense polynucleotide to the protein-encoding sequence.

Group X, claim 16 drawn to a use of the compound obtained from a screening method for regulation of sugar production.

Group XI, claim 17 drawn to a method of detecting diabetes.

Group XII, claim 19 drawn to a method of screening a sugar production-regulating substance.

2. Upon thorough consideration of the claims, the examiner has determined that a lack of unity of invention exists, as defined in Rule 13.

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. Annex B, Part 1(b), indicates that "special technical features" means those technical features which as a whole define a contribution over the prior art. The inventions listed as Groups I and II are directed to polynucleotide sequences and their expressed proteins. These inventions share the common special technical feature of polynucleotide sequence encoding a polypeptide. This common special technical feature is not a contribution over the prior art as polynucleotide sequences ID #AK002457 and #AK080857 are deposited (see appendix A) and taught by Carninci *et al.* (Meth. Enzymol. (1999) 303:19-44) and Carninci *et al.* (Genome Res. (2000) 10 (10), 1617-1630), respectively. Thus the invention of Groups I and II lack unity of invention.

Restriction Requirement Applicable to all Groups

Furthermore, in claims 1-19 the presence of multiple polypeptide sequences and polynucleotide sequences, each with a different SEQ ID NO: allows for a variety of patentably distinct products. Depending on the sequence of each polypeptide and polynucleotide, the characteristics of the resulting molecule will vary in regards to structure and function. Each one of these polypeptides is capable of eliciting a specific immune response and can be used to produce a specific antibody; also each one of the mentioned polynucleotides is capable of hybridizing to different probes and is capable of encoding a characteristically different peptide in regards to structure and activity. Therefore these polypeptides and polynucleotides are patentably distinct absent factual

evidence to the contrary. Applicant is required under 35 U.S.C. 121 to elect a single SEQ ID NO: for prosecution on the merits.

Applicant is advised that a reply to this requirement must include an identification of SEQ ID NO: that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. The applicant should be aware that selection of a single SEQ ID NO: represents a response to a restriction requirement, not an election of species.

3. The inventions are distinct, each from the other because of the following reasons:

The polynucleotide of Group I and polypeptide of group II are independent and distinct because polynucleotides, which are composed of purine and pyrimidine units, and polypeptides, which are composed of amino acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of Group I does not necessarily encode a polypeptide of Group II. For example, as disclosed in the specification, SEQ ID NO:2 is 327 amino acids in length, whereas the nucleic acid molecule in SEQ ID NO:1 is 1061 nucleotides. The genetic information in SEQ ID NO:1 could have different codons which code for the same amino acid comprising SEQ ID NO:2. Furthermore, while a polypeptide of Group II can be made by methods using some, but not all, of the polynucleotides that fall within the scope of Group I, it can also be recovered from a natural source using biochemical

means. For instance, the polypeptide can be isolated using affinity chromatography or can even be made synthetically.

Furthermore, searching the inventions of Groups I and II together would impose a serious search burden. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In addition, the polypeptide claims include polypeptides having 88% identity to the sequence identified. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. As such it would be burdensome to search the inventions of Groups I and II together.

The polynucleotide of Group I and the antibody of Group IV are related by virtue of the protein that is encoded by the polynucleotide and necessary for the production of the antibody. However, the polynucleotide itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

The polypeptide of Group II and the antibody of Group IV are patentably distinct for the following reasons. The protein of Group II is related to the antibody of Group IV by virtue of being the cognate antigen necessary for the production of antibody. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because the protein can be used in other, materially different processes from the production of antibody such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of

the protein if it is a receptor. Further, a protein and its cognate antibody are structurally and functionally distinct molecules with different amino acid compositions.

The polynucleotide and the polypeptide of Groups I and II and the screening methods of Group VI-VII and XII are related because the polynucleotide encodes one of the proteins used in the screening method. Clearly, the polynucleotide is not required for the practice of the screening method, nor are the polynucleotide and protein disclosed as capable of use together. Thus, notwithstanding the relationship, these inventions are patentably distinct.

Inventions of Groups II, IV-V, VIII-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as being capable of use together and have different modes of operation, each being used in different capacities, have different functions and produce different effects.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed. (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention,

the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawn Hamidinia whose telephone number is (571) 272-4534. The examiner can normally be reached on Mon-Fri from 9:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SAH

JON WEBER
SUPERVISORY PATENT EXAMINER